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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,013	03/16/2004	Bruce F. Molino	20011/1331	4932

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,013	MOLINO ET AL.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-188 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-188 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-103, drawn to a compound of Formula (I), classified, e.g., in class 514, subclass 11.

II. Claims 104-133, drawn to a process for the preparation of a compound of Formula (III), classified in, e.g., in class 514, subclass 1+.

III. Claims 134-135, drawn to a process for the preparation of a compound of Formula (V), classified in, e.g., in class 514, subclass 1+.

IV. Claims 136-137, drawn to a second process for the preparation of a compound of Formula (V), classified in, e.g., in class 514, subclass 1+.

V. Claims 138-140, drawn to a process for the preparation of a compound of Formula (VI), classified in, e.g., in class 514, subclass 1+.

VI. Claims 141-142, drawn to a process for the preparation of a compound, classified in, e.g., class 514, subclass 1+.

VII. Claims 143-147, drawn to a process for the preparation of a compound, classified in, e.g., class 514, subclass 1+.

VIII. Claims 148-154, drawn to a process for the preparation of a compound, classified in, e.g., class 514, subclass 1+.

IX. Claims 155-157, drawn to a process for the preparation of a compound, classified in, e.g., class 514, subclass 1+.

X. Claims 158-160, drawn to a process for the preparation of a compound of Formula (IX), classified in, e.g., class 514, subclass 1+.

XI. Claims 161-164, drawn to a process for the preparation of a compound, classified in, e.g., class 514, subclass 1+.

XII. Claims 165-173, drawn to a process for the preparation of a compound of Formula (XI), classified in, e.g., class 514, subclass 1+.

XIII. Claims 174-182, drawn to a process for the preparation of a compound of Formula (VI), classified in, e.g., class 514, subclass 1+.

XIV. Claim 183, drawn to a method of suppressing or reducing immune response in a mammal, classified in, e.g., class 514, subclass 11.

XV. Claims 184-185, drawn to a method of treating a mammal with chronic inflammatory or autoimmune disease, classified in, e.g., class 514, subclass 11.

XVI. Claims 186-187, drawn to a method of treating a mammal with a neurodegenerative disease, classified in, e.g., class 514, subclass 11.

XVII. Claim 188, drawn to a method of treating a mammal with infectious diseases caused by HIV, fungal pathogens, or parasites, classified in, e.g., class 514, subclass 11.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups II-XVII are directed to different inventions which are not connected in design, operation, or effect. These methods are independent since they

are not disclosed as capable of use together, they have different modes of operation, they have different functions, and they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

Inventions I and II-XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the instantly claimed cyclic peptides may also be made using, e.g., solid phase resin methods.

Inventions I and XIV-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as evidenced by the claims themselves, the claimed cyclic peptides may be used for treating neurodegenerative diseases and for treating infections with fungal pathogens.

The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one Group would not necessarily anticipate or even make obvious another Group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for each Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In addition, this application contains claims directed to the following patentably distinct species of the claimed invention: the many and multiple cyclic polypeptides instantly claimed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species [i.e., elect a single compound of Formula I with any and all substituents: A, B, C, D, E, F, G, H, I, J, K, R_1, X, R_0 and so forth, fully accounted for] prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 104, 134, 136, 138, 141, 143, 148, 155, 158, 161, 165, 174, 183, 184, 186 and 188 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcela M Cordero Garcia

Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 10/05

CHRISTOPHER R. TATE
PRIMARY EXAMINER